Remarks

Claims 41-51 are pending in this application. No claim amendments are made in this paper, and thus, no new matter has been introduced.

A new rejection under 35 U.S.C. § 103 is raised in the Office Action. Applicant respectfully submits that this rejection should be withdrawn for at least the following reasons.

A. The Rejection Under 35 U.S.C. § 103 Should Be Withdrawn

On pages 5-9 of the Office Action, claims 41-51 are rejected over Scott *et al.*, *Br. J. Pharmacol.*, 111: 97-102 (1994) ("Scott"), in view of WO 94/00114 by Young *et al.* ("Young") and Adda *et al.*, *Arq. Neuropsiquiatr.* 55(3A): 423-6 (1997) (abstract only) ("Adda"). Applicant respectfully traverses this rejection.

It appears that the new rejection differs from the previous rejection in that the new rejection relies on an additional reference, Adda. In this regard, the Examiner alleges that, because Adda allegedly teaches that "the main symptoms of narcolepsy include excessive daytime sleepiness and catalepsy and that depressive complaints are occasionally reported," it would have been obvious to "use the optically pure (S) form of BTS 54 505 ... as taught by [Scott] to treat narcolepsy as taught by [Adda] to control symptoms of depression." (Office Action, page 8). Applicant disagrees with this allegation at least because: (1) Scott does not teach or suggest optically pure (S) form of didesmethylsibutramine; and (2) Adda's report that narcolepsy is "occasionally" associated with depressive symptoms cannot be extrapolated to a suggestion that anti-depressants should be used to "treat narcolepsy."

First, Applicant again respectfully points out that none of the cited references discloses or suggests the use of enantiomerically pure (S)-didesmethylsibutramine. In this regard, Applicant repeatedly pointed out that, while Scott discloses racemic didesmethylsibutramine, it does not disclose (S) isomer of didesmethylsibutramine. This submission is acknowledged by the Examiner in "Response to applicant's arguments/remarks" section of the Office Action, and based at least partly on this submission, the Examiner indicates that "the rejection is withdrawn" in response. (Office Action, pages 2-3). The fact that Scott does not disclose optically pure (S) isomer of didesmethylsibutramine is also recognized in the current rejection. (*Id.*, page 7). Despite this, the "new rejection" is partly based on the same allegation, and no explanation other than the Examiner's conclusory statement that it could have been obvious "to use the optically pure (S) form of [didesmethylsibutramine] as taught by" Scott. (*Id.*, page 8)

(emphasis in original). Presumably, by underlying the word "the," the Examiner appears to imply that the optically pure (S) isomer of didesmethylsibutramine, the very compound recited by the pending claims, is disclosed in Scott. However, this assertion is not only incorrect, but also wholly inconsistent with the recognition made in other parts of the Office Action that Scott does not teach the optically pure isomer of didesmethylsibutramine. (*See* Office Action, page 7).[1]

Second, and perhaps more importantly, Applicant respectfully points out that none of the references cited in the Office Action discloses anything about the use of an anti-depressant, much less enantiomerically pure (S)-didesmethylsibutramine, for the treatment of narcolepsy. In particular, Adda, which is the reference provided in the Office Action in this regard, falls far short of teaching or suggesting using an anti-depressant for the treatment of narcolepsy.

Adda clearly discloses that depression is not a major symptom commonly associated with all narcolepsy patients. Adda further discloses that 75% of the studied cases showed no depressive disorder and concluded that there is no correlation between narcolepsy and major depression. (*See* Adda). Thus, Adda would not have prompted a person of ordinary skill in the art to use an anti-depressant, much less enantiomerically pure (S)-didesmethylsibutramine, for the treatment of narcolepsy. If anything, Applicant respectfully points out that Adda, by disclosing that there is no correlation between narcolepsy and depression, would have discouraged those skilled in the art from using anti-depressants for the treatment of narcolepsy.

Moreover, case law clearly supports that the patentability of claims to the treatment of a disorder is not negated by prior disclosure of the treatment of the symptoms associated with the disorder. (*See, e.g., Rapoport v. Dement*, 254 F.3d 1053, 1060-1061 (Fed. Cir. 2001) (holding that claims to the treatment of sleep apneas using a compound were not anticipated by or obvious over prior art disclosure of the treatment of symptoms associated with sleep apnea using the same compound, because the reference's mention of the possibility of administering the compound to patients suffering from sleep apnea was "for the purpose of treating [a symptom] in such patients, not for the purpose of treating the sleep apnea disorder itself.")). Thus, even assuming, *arguendo*, Adda's disclosure somehow suggested a connection between depression and narcolepsy, the use of an anti-depressant to treat depression as a symptom of narcolepsy would not have rendered the use of an anti-depressant to treat narcolepsy obvious, because any administration of an anti-

[1] In addition, while the Office Action provides Young as another reference, the Office Action recognizes that Young also "does not teach optically pure (-) didesmethylsibutramine." (Office Action, page 8).

depressant would have been "for the purpose of treating [depression]," but not for the purpose of treating narcolepsy. (*Id.*). For at least these reasons, Applicant respectfully submits that the rejection should be withdrawn.

Finally, Applicant respectfully reiterates that the blanket statement that stereochemical purity is of importance in the field of pharmaceuticals since certain isomers may actually be deleterious and not simply inert cannot form a basis to render the claimed use of the particular enantiomer recited by the pending claims obvious. This is because there is no basis to "predict with a reasonable expectation of success whether one enantiomer of [the claimed compound] would have better pharmaceutical properties than the racemate itself." (*See Sanofi-Synthelabo, v. Apotex, Inc.*, 492 F.Supp.2d 353, 390 (S.D.N.Y 2007)). Accordingly, Applicant respectfully submits that the rejection should be withdrawn for this additional reason.

B. Conclusion

For at least the foregoing reasons, Applicant submits that all of the pending claims are allowable, and thus, respectfully requests that the rejection of the claims under 35 U.S.C. § 103 be withdrawn.

No fee is believed due for the submission of this paper. If any fees are required, however, the Director is authorized to charge them to Deposit Account No. 50-3013.

Respectfully submitted,

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